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Quality by Design (QbD) in Clinical Trials

Quality by design is not a new concept, it was first introduced by Joseph Juran, a well-known quality expert; the concept was and still is utilized by the automotive industry. Janet Woodcock of the Food and Drug Administration (FDA) defined pharmaceutical quality "as a product that is free of contamination and reproducibly delivers the therapeutic benefit promised in the label to the consumer". The FDA's emphasis on quality by design began with the recognition that increased testing does not improve product quality. Quality is an attitude, perhaps, it is thinking without thinking.
To ensure we all have the same understanding of what QbD is; here is the standard definition for the Pharmaceutical Industry; Quality by Design (QbD) "is a systematic approach to pharmaceutical development that begins with predefined objectives and emphasizes product and process understanding and process control, based on sound science and quality risk management".

How does QbD apply to clinical trials? For starters, a quality strategy has to be embraced by senior management and those involved in the clinical trial. Also, implementing a monitoring plan and a quality plan that is communicated frequently and followed consistently is essential; here is a example of a quality plan, this is only an example thus, you may want to customize this plan in order for it to meet your needs http://tinyurl.com/ofex78k .
In discussing Quality by Design in the Pharmaceutical space I must also mention the Target Product Profile (TPP). The purpose of a TPP is to provide a format for discussions between a sponsor and the FDA that can be used throughout the drug development process, from investigational new drug application (IND) through post-marketing. " The TPP embodies the notion of beginning with the goal in mind. The ideal version of what the sponsor would like to claim in labeling guides the design, conduct, and analysis of clinical trials to maximize the efficiency of the development program". Ideally, the final version of the TPP will be similar to the annotated draft labeling submitted with a new drug application (NDA) or biologics license application (BLA).

There was a presentation that the FDA developed several years ago about QbD that may be worth viewing, http://tinyurl.com/newa3kz

ABOUT AUTHOR

Kathryn's passion has always been in the Life Sciences, both in pre-clinical and clinical drug development. Starting her pre-clinical work at Duke University, Kathryn continued to develop her skills at Becton Dickinson & Co., a biological research laboratory in Durham, N.C. After six years at Becton Dickinson, she accepted a Clinical Research Associate (CRA) position at Bristol Myers Squibb, eventually advancing to senior leadership positions in clinical drug development.

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